

Appl. No. 09/599,624
Atty. Docket No. 8135&
Amdt. dated September 22, 2004
Reply to Office Action of March 22, 2004

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (previously presented) A topical composition for treating microbes, in order to inhibit or prevent the growth on the skin or scalp of said microbes, comprising:

- a) from about 0.001% to about 10%, by weight of the composition, of an anti-microbial active selected from the group consisting of polyvalent metal salts of pyrithione;
- b) from greater than about 1% to about 10%, by weight of the composition, of a metal ion source selected from group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts, and mixtures thereof; and
- c) a topical carrier for the anti-microbial active and the metal salt;

wherein the weight ratio of the metal source to the anti-microbial active is from about 5:100 to about 5:1 and wherein at least 50% of the anti-microbial active is insoluble in the composition.

2. (original) A topical composition according to Claim 1, wherein the polyvalent metal salt of pyrithione is selected from the group consisting of magnesium pyrithione, barium pyrithione, bismuth pyrithione, strontium pyrithione, copper pyrithione, zinc pyrithione, cadmium pyrithione, zirconium pyrithione and mixtures thereof.

3. (original) A topical composition according to Claim 2, wherein the polyvalent metal salt of pyrithione is selected from the group consisting of zinc pyrithione, copper pyrithione, and mixtures thereof.

4. (original) A topical composition according to Claim 3, wherein the polyvalent metal salt of pyrithione is zinc pyrithione.

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5. (original) A topical composition according to Claim 4, wherein the composition comprises from about 0.1% to about 2%, by weight of the composition, of the zinc pyrithione.
6. (original) A topical composition according to Claim 1, wherein the metal ion source is selected from the group consisting of zinc acetate, zinc oxide, zinc carbonate, zinc hydroxide, zinc chloride, zinc sulfate, zinc citrate, zinc fluoride, zinc iodide, zinc lactate, zinc oleate, zinc oxalate, zinc phosphate, zinc propionate, zinc salicylate, zinc selenate, zinc silicate, zinc stearate, zinc sulfide, zinc tannate, zinc tartrate, zinc valerate, zinc gluconate, zinc undecylate, copper disodium citrate, copper triethanolamine, copper carbonate, cuprous ammonium carbonate, cupric hydroxide, copper chloride, cupric chloride, copper ethylenediamine complex, copper oxychloride, copper oxychloride sulfate, cuprous oxide, copper thiocyanate, colloidal silver, silver bromide, silver chloride, silver citrate, silver iodide, silver lactate, silver nitrate, silver oxide, silver picrate, and mixtures thereof.
7. (original) A topical composition according to Claim 1, wherein the metal ion source is selected from the group consisting of zinc salts, copper salts and mixtures thereof.
8. (original) A topical composition according to Claim 7, wherein the metal ion source is selected from the group consisting of soluble zinc salts, soluble copper salts, and mixtures thereof.
9. (original) A topical composition according to Claim 8, wherein the metal ion source is selected from copper sulfate, zinc sulfate, and mixtures thereof.
10. (previously presented) A topical composition according to Claim 7, wherein the composition comprises from greater than about 1% to about 2%, by weight of the composition, of the metal ion source.
11. (original) A topical composition according to Claim 1 wherein at least 99.99% of the anti-microbial active is insoluble in the composition.
12. (original) A topical composition according to Claim 1, wherein 100% of the anti-microbial active is insoluble in the composition.
13. (original) A topical composition according to Claim 1, wherein less than 50% of the polyvalent metal salt disassociates into free pyrithione ion in the composition.

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14. (original) A topical composition according to Claim 13, wherein less than 5% of the polyvalent metal salt disassociates into free pyrrithione ion in the composition.

15. (currently amended) A topical composition for treating microbes, in order to inhibit or prevent the growth on the skin or scalp of said microbes, comprising:

- a) from about 0.001% to about 10%, by weight of the composition, of an anti-microbial active selected from the group consisting of polyvalent metal salts of pyrrithione;
- b) from about 0.001% to about 10%, by weight of the composition, of a metal ion source selected from group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts, and mixtures thereof;
and
- c) a topical carrier for the anti-microbial active and the metal salt;

wherein the weight ratio of the metal source to the anti-microbial active is from about 5:100 to about 5:1 and wherein at least 50% of the anti-microbial active is insoluble in the composition and further A topical composition according to Claim 1, wherein the composition comprises at least a 5 to 1 ratio of polyvalent metal salt of pyrrithione to a strong chelating agent wherein the strong chelating agent is selected from the group consisting of di- or polyamines, diethylene triamine penta-acetic acid, tetraethylene triamine, ethylene diamine, diethylene triamine or salts thereof or mixtures thereof.

16. (currently amended) A topical composition according to Claim 15, wherein the composition is free of a strong chelating agent.

17. (original) A topical composition according to Claim 1, wherein the composition further comprises from about 7% to about 30%, by weight of the composition, of a deterative surfactant selected from the group consisting of anionic surfactants, amphoteric surfactants, zwitterionic surfactants, and mixtures thereof.

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18. (original) A topical composition according to Claim 17 wherein the deterative surfactant is an anionic surfactant.

19. (original) A topical composition according to Claim 1, wherein the composition further comprises a conditioning agent.

20. (original) A topical composition according to Claim 1, wherein the composition further comprises a cationic styling polymer and a cationic deposition polymer.

21. (original) A topical composition according to Claim 1, wherein the composition is a hair styling shampoo and wherein the composition further comprises a cationic spreading agent.

22. (original) A topical composition according to Claim 1, wherein the composition further comprises a polyalkylene glycol.

23. (original) A topical composition according to Claim 1, wherein the composition further comprises an additional anti-microbial active selected from the group consisting of ketoconazole, intraconazole, coal tar, selenium sulfide, and mixtures thereof.

24. (original) A topical composition according to Claim 1, wherein the composition further comprises a hair growth active.

25. (original) A topical composition according to Claim 19, wherein the conditioning agent is selected from the group consisting of cationic polymers, polyolefins, hydrocarbon oils, silicone gums, silicone oils, and mixtures thereof.

26. (previously presented) A topical anti-dandruff composition comprising:

- a) from about 0.1% to about 2%, by weight of the composition, of zinc pyrithione;
- b) from greater than about 1% to about 5%, by weight of the composition, of a metal ion source useful for increasing efficacy of zinc pyrithione selected from the group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts;
- c) a topical carrier for said zinc pyrithione and said metal ion source;

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wherein the weight ratio of the metal source to the anti-microbial active is from about 5:100 to about 5:1 and wherein at least 50% of the zinc pyrithione is insoluble in the composition.

27. (original) An anti-dandruff composition according to Claim 26, wherein the metal ion source is selected from zinc acetate, zinc oxide, zinc carbonate, zinc hydroxide, zinc chloride, zinc sulfate, zinc citrate, zinc fluoride, zinc iodide, zinc lactate, zinc oleate, zinc oxalate, zinc phosphate, zinc propionate, zinc salicylate, zinc selenate, zinc silicate, zinc stearate, zinc sulfide, zinc tannate, zinc tartrate, zinc valerate, zinc gluconate, zinc undecylate, copper disodium citrate, copper triethanolamine, copper carbonate, cuprous ammonium carbonate, cupric hydroxide, copper chloride, cupric chloride, copper ethylenediamine complex, copper oxychloride, copper oxychloride sulfate, cuprous oxide, copper thiocyanate, colloidal silver, silver chloride, silver citrate, silver iodide, silver lactate, silver nitrate, silver oxide, silver picrate, and mixtures thereof.

28. (previously presented) A shampoo composition useful for improving the appearance of scalp exhibiting dandruff symptoms, said composition comprising:

- a) from about 0.3% to about 2%, by weight of the composition, of zinc pyrithione;
- b) from greater than about 1% to about 5%, by weight of the composition, of a metal ion source selected from the group consisting of zinc acetate, zinc oxide, zinc carbonate, zinc hydroxide, zinc chloride, zinc sulfate, zinc citrate, zinc fluoride, zinc iodide, zinc lactate, zinc oleate, zinc oxalate, zinc phosphate, zinc propionate, zinc salicylate, zinc selenate, zinc silicate, zinc stearate, zinc sulfide, zinc tannate, zinc tartrate, zinc valerate, zinc gluconate, zinc undecylate, copper disodium citrate, copper triethanolamine, copper carbonate, cuprous ammonium carbonate, cupric hydroxide, copper chloride, cupric chloride, copper ethylenediamine complex, copper oxychloride, copper oxychloride sulfate, cuprous oxide, copper thiocyanate, and mixtures thereof;
- c) a topical carrier for said zinc pyrithione and said metal ion source; and
- d) a deterative surfactant;

wherein the weight ratio of the metal source to the anti-microbial active is from about 5:100 to about 5:1 and wherein at least 50% of the zinc pyrithione is insoluble in the composition.

29. (original) A topical composition according to Claim 1 wherein the composition further comprises a solid cosmetic carrier.

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30. (original) A topical composition according to Claim 29 wherein the solid cosmetic carrier is talc.

31. (withdrawn) A method of treating athlete's foot comprising the application of a safe and effective amount of the topical composition of Claim 1 to the feet of a person in need of such treatment.

32. (withdrawn) A method of treating microbial infections comprising applying to the skin of mammal in need of treatment a safe and effective amount of the composition of Claim 1.

33. (withdrawn) A method of improving the appearance of hair or scalp, said method comprising the steps of topically applying to hair or scalp in need of treatment a composition according to Claim 4.

34. (withdrawn) A method of treating fungal infections on the skin or scalp comprising applying to the scalp of mammal in need of treatment a safe and effective amount of the composition of Claim 26.

35. (withdrawn) A method of treating dandruff comprising applying to the scalp of mammal in need of treatment a safe and effective amount of the composition of Claim 13.

36. (previously presented) A topical anti-microbial composition prepared by the process of mixing:

- a) from about 0.1% to about 2%, by weight of the composition, of an anti-microbial active selected from the group consisting of polyvalent metal salts of pyrithione;
- b) from greater than about 1% to about 5%, by weight of the composition, of a metal ion source selected from group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts, and mixtures thereof; and
- c) a topical carrier for the anti-microbial active and the metal salt; wherein the weight ratio of the metal source to the anti-microbial active is from about 5:100 to about 5:1 and wherein at least 50% of the anti-microbial active is insoluble in the composition.

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37. (original) A topical anti-microbial composition according to Claim 36 wherein the polyvalent metal salt is zinc pyrithione and the metal ion source is selected from the group consisting of zinc salts, copper salts, and mixtures thereof.

38. (original) A topical anti-microbial composition according to Claim 37 wherein at least 99.9% of the anti-microbial active is insoluble in the composition.

39. (withdrawn) A method of regulating hair growth or re-growth, said method comprising the step of:

- a) applying to the scalp of a mammal in need of treatment, a safe and effective amount of the composition of Claim 4.

40. (withdrawn) A method of stimulating hair growth, said method comprising the step of:

- a) applying to the scalp of a mammal in need of treatment, a safe and effective amount of the composition of Claim 4.

41. (withdrawn) A method of inhibiting or reducing hair loss, said method comprising the step of:

- a) applying to the scalp of a mammal in need of treatment, a safe and effective amount of the composition of Claim 4.

42. (previously presented) The topical composition of Claim 1 wherein said metal ion source is zinc oxide.

43. (previously presented) A topical composition for treating microbes, in order to inhibit or prevent the growth on the skin or scalp of said microbes, comprising:

- a) from about 0.001% to about 10%, by weight of the composition, of zinc pyrithione;
- b) from about 0.001% to about 10%, by weight of the composition, of zinc oxide;
- and
- c) a topical carrier for the zinc pyrithione and zinc oxide;

wherein the weight ratio of the zinc oxide to the zinc pyrithione is from about 5:100 to about 5:1 and wherein at least 50% of the zinc pyrithione is insoluble in the composition.

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44. (previously presented) The topical composition of Claim 43, wherein the composition comprises from about 0.1% to about 2%, by weight of the composition, of the zinc pyrithione.

45. (previously presented) The topical composition of Claim 43, wherein the composition comprises from about 0.1% to about 2%, by weight of the composition, of the zinc oxide.

46. (previously presented) The topical composition of Claim 44, wherein the composition comprises from about 0.1% to about 2%, by weight of the composition, of the zinc oxide.

47. (previously presented) A topical composition for treating microbes, in order to inhibit or prevent the growth on the skin or scalp of said microbes, comprising:

- a) from about 0.001% to about 10%, by weight of the composition, of an anti-microbial active selected from the group consisting of polyvalent metal salts of pyrithione;
- b) from about 1.5% to about 10%, by weight of the composition, of a metal ion source selected from group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts, and mixtures thereof; and
- c) a topical carrier for the anti-microbial active and the metal salt;

wherein the weight ratio of the metal source to the anti-microbial active is from about 5:100 to about 5:1 and wherein at least 50% of the anti-microbial active is insoluble in the composition.

48. (withdrawn) A method of treating microbial infections on the skin or scalp, said method comprising the step of:

- a) applying to the skin or scalp of a mammal in need of treatment, a safe and effective amount of the composition of Claim 1; and
- b) leaving the composition on the skin or scalp for a sufficient amount of time to allow for efficacy.

49. (withdrawn) A method of treating microbial infections on the skin or scalp, said method comprising the step of:

- a) applying to the scalp of a mammal in need of treatment, a safe and effective amount of the composition of Claim 19.

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50. (withdrawn) A method of treating microbial infections on the skin or scalp, said method comprising the step of:

- a) applying to the scalp of a mammal in need of treatment, a safe and effective amount of the composition of Claim 20.

51. (withdrawn) A topical composition for treating microbes, in order to inhibit or prevent the growth on the skin or scalp of said microbes, comprising:

- a) from about 0.001% to about 10%, by weight of the composition, of an anti-microbial active selected from the group consisting of polyvalent metal salts of pyrrithione;
- b) from about 0.001% to about 10%, by weight of the composition, of a metal ion source selected from group consisting of copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts, and mixtures thereof; and
- c) a topical carrier for the anti-microbial active and the metal salt;

wherein the weight ratio of the metal source to the anti-microbial active is from about 5:100 to about 5:1 and wherein at least 50% of the anti-microbial active is insoluble in the composition.

52. (previously presented) A topical composition for treating microbes, in order to inhibit or prevent the growth on the skin or scalp of said microbes, comprising:

- a) from about 0.001% to about 10%, by weight of the composition, of an anti-microbial active selected from the group consisting of polyvalent metal salts of pyrrithione;
- b) from about 0.001% to about 10%, by weight of the composition, of a metal ion source selected from group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts, and mixtures thereof; and
- c) a topical carrier for the anti-microbial active and the metal salt;

wherein the weight ratio of the metal source to the anti-microbial active is from about 5:100 to about 5:1 and wherein at least 50% of the anti-microbial active is insoluble in the composition and further wherein the composition is free of from about 1 ppm to about 30 ppm of a preservative selected from the group consisting of 5-choloro-2-alkyl-4-isothiazolin-3-one, 2-alkyl-4-isothiazolin-3-one, wherein the alkyl is selected from the group consisting of methyl, ethyl, butyl, propyl and mixtures thereof.

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53. (previously presented) A topical composition for treating microbes, in order to inhibit or prevent the growth on the skin or scalp of said microbes, comprising:

- a) from about 0.001% to about 10%, by weight of the composition, of an anti-microbial active selected from the group consisting of polyvalent metal salts of pyrithione;
- b) from about 0.5% to about 10%, by weight of the composition, of a metal ion source selected from group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts, and mixtures thereof; and
- c) a topical carrier for the anti-microbial active and the metal salt;

wherein the weight ratio of the metal source to the anti-microbial active is from about 5:100 to about 5:1 and wherein at least 50% of the anti-microbial active is insoluble in the composition.

54. (previously presented) A topical composition for treating microbes, in order to inhibit or prevent the growth on the skin or scalp of said microbes, comprising:

- a) from about 0.001% to about 10%, by weight of the composition, of an anti-microbial active selected from the group consisting of polyvalent metal salts of pyrithione;
- b) from about 2% to about 10%, by weight of the composition, of a metal ion source selected from group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts, and mixtures thereof; and
- c) a topical carrier for the anti-microbial active and the metal salt;

wherein the weight ratio of the metal source to the anti-microbial active is from about 5:100 to about 5:1 and wherein at least 50% of the anti-microbial active is insoluble in the composition.

55. (previously presented) A topical composition for treating microbes, in order to inhibit or prevent the growth on the skin or scalp of said microbes, consisting essentially of:

- a) from about 0.001% to about 10%, by weight of the composition, of an anti-microbial active selected from the group consisting of polyvalent metal salts of pyrithione;
- b) from about 0.001% to about 10%, by weight of the composition, of a metal ion source selected from group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts, and mixtures thereof; and
- c) a topical carrier for the anti-microbial active and the metal salt;

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wherein the weight ratio of the metal source to the anti-microbial active is from about 5:100 to about 5:1 and wherein at least 50% of the anti-microbial active is insoluble in the composition.

56. (previously presented) A topical composition for treating microbes, in order to inhibit or prevent the growth on the skin or scalp of said microbes, comprising:

- a) from about 0.001% to about 10%, by weight of the composition, of an anti-microbial active consisting essentially of polyvalent metal salts of pyrithione;
- b) from about 0.001% to about 10%, by weight of the composition, of a metal ion source selected from group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts, and mixtures thereof; and
- c) a topical carrier for the anti-microbial active and the metal salt;

wherein the weight ratio of the metal source to the anti-microbial active is from about 5:100 to about 5:1 and wherein at least 50% of the anti-microbial active is insoluble in the composition.

57. (currently amended) A topical composition for treating microbes, in order to inhibit or prevent the growth on the skin or scalp of said microbes, ~~consisting of~~ comprising:

- a) from about 0.001% to about 10%, by weight of the composition, of an anti-microbial active consisting of polyvalent metal salts of pyrithione;
- b) from about 0.001% to about 10%, by weight of the composition, of a metal ion source selected from group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts, and mixtures thereof; and
- c) a topical carrier for the anti-microbial active and the metal salt;

wherein the weight ratio of the metal source to the anti-microbial active is from about 5:100 to about 5:1 and wherein at least 50% of the anti-microbial active is insoluble in the composition.

58. (new) A topical composition for treating microbes, in order to inhibit or prevent the growth on the skin or scalp of said microbes, consisting essentially of:

- a) from about 0.001% to about 10%, by weight of the composition, of an anti-microbial active selected from the group consisting of polyvalent metal salts of pyrithione;
- b) from about 0.01% to about 5%, by weight of the composition, of a metal ion source selected from group consisting of zinc salts, copper salts, silver salts,

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nickel salts, cadmium salts, mercury salts, bismuth salts, and mixtures thereof;
and

c) a topical carrier for the anti-microbial active and the metal salt;

wherein the weight ratio of the metal source to the anti-microbial active is from about 2:10 to about 3:1 and wherein at least 50% of the anti-microbial active is insoluble in the composition.

59. (new) A topical composition for treating microbes, in order to inhibit or prevent the growth on the skin or scalp of said microbes, comprising:

a) from about 0.001% to about 10%, by weight of the composition, of an anti-microbial active consisting essentially of polyvalent metal salts of pyrithione;

b) from about 0.01% to about 5%, by weight of the composition, of a metal ion source selected from group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts, and mixtures thereof;
and

c) a topical carrier for the anti-microbial active and the metal salt;

wherein the weight ratio of the metal source to the anti-microbial active is from about 2:10 to about 3:1 and wherein at least 50% of the anti-microbial active is insoluble in the composition.

60. (new) A topical composition for treating microbes, in order to inhibit or prevent the growth on the skin or scalp of said microbes, consisting of:

a) from about 0.001% to about 10%, by weight of the composition, of an anti-microbial active consisting of polyvalent metal salts of pyrithione;

b) from about 0.01% to about 5%, by weight of the composition, of a metal ion source selected from group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts, and mixtures thereof;
and

c) a topical carrier for the anti-microbial active and the metal salt;

wherein the weight ratio of the metal source to the anti-microbial active is from about 2:10 to about 3:1 and wherein at least 50% of the anti-microbial active is insoluble in the composition.

61. (new) A topical composition for treating microbes, in order to inhibit or prevent the growth on the skin or scalp of said microbes, consisting essentially of:

a) from about 0.001% to about 10%, by weight of the composition, of an anti-microbial active selected from the group consisting of polyvalent metal salts of pyrithione;

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- b) from about 0.1% to about 2%, by weight of the composition, of a metal ion source selected from group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts, and mixtures thereof; and
- c) a topical carrier for the anti-microbial active and the metal salt;

wherein the weight ratio of the metal source to the anti-microbial active is from about 1:2 to about 2:1 and wherein at least 50% of the anti-microbial active is insoluble in the composition.

62. (new) A topical composition for treating microbes, in order to inhibit or prevent the growth on the skin or scalp of said microbes, comprising:

- a) from about 0.001% to about 10%, by weight of the composition, of an anti-microbial active consisting essentially of polyvalent metal salts of pyrithione;
- b) from about 0.1% to about 2%, by weight of the composition, of a metal ion source selected from group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts, and mixtures thereof; and
- c) a topical carrier for the anti-microbial active and the metal salt;

wherein the weight ratio of the metal source to the anti-microbial active is from about 1:2 to about 2:1 and wherein at least 50% of the anti-microbial active is insoluble in the composition.

63. (new) A topical composition for treating microbes, in order to inhibit or prevent the growth on the skin or scalp of said microbes, consisting of:

- a) from about 0.001% to about 10%, by weight of the composition, of an anti-microbial active consisting of polyvalent metal salts of pyrithione;
- b) from about 0.1% to about 2%, by weight of the composition, of a metal ion source selected from group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts, and mixtures thereof; and
- c) a topical carrier for the anti-microbial active and the metal salt;

wherein the weight ratio of the metal source to the anti-microbial active is from about 1:2 to about 2:1 and wherein at least 50% of the anti-microbial active is insoluble in the composition.

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